

REMARKS

This is responsive to the Office Action mailed August 30, 2004. Applicant has canceled claims 2 and 7-10. Claim 1 has been amended to incorporate the limitation of claim 2. No new matter has been added.

Rejections Under 35 U.S.C. 103

The Examiner rejected claims 1-12 under 35 U.S.C. § 103 as unpatentable over three separate references: JP 08-157365, JP 10-045570 and US patent 5,866,157. Each of the rejections has the same basis, namely that the reference teaches a percutaneous adhesive preparation in which the disclosed thickness of an adhesive film implies that particle size of powdered organic acid cannot be more than 100 micrometers in diameter. The Examiner suggests that one of ordinary skill in the art would have been motivated to select sodium acetate having particle sizes less than 50 micrometers (or 100 micrometers on page 6 of the Office Action) motivated by the references' teaching that "such preparation has remarkable high skin permeation rate and remarkable reduced skin irritation." (Office Action at p.4, similar recitations on pages 5 and 6). Applicant respectfully requests reconsideration.

The references do not teach the invention

The Examiner acknowledges that the references do not expressly disclose that the organic acid is in powder form, and if so, a particular diameter or range of diameters of particles. Thus there is no explicit "teaching" of preparations having particle sizes of less than 100 μm or less than 50 μm as suggested by the Examiner. The Examiner indicated that this teaching was implied from the thickness of the adhesive film that contains the components of the preparations recited in the references. Applicant has amended claim 1 to incorporate the limitation of claim 2, such that the range of the organic acid salt particle diameters claimed is now 0.1-10 μm . The references cited by the Examiner do not teach this range, nor do they fairly suggest it.

There is no motivation to modify the teachings of the references

The Examiner suggests that one of ordinary skill in the art would be motivated to use particles of less than 50 μm or 100 μm by the teaching of the references of high skin permeation rates and reduced skin irritation. Applicant respectfully disagrees.

Taking the '157 patent as an example, there is no teaching whatsoever of particle sizes; the Examiner has implied that the reference teaches particles of a particular size. Even if this were sufficient to teach one of ordinary skill in the art, which Applicant has disputed above, it is not a sufficient teaching to motivate the skilled artisan to use particles of that diameter, because there is no link between particle size and effect made in the '157 patent. The '157 patent attributes the enhanced effects of the invention to "formulating a physiological active substance, an organic acid and an absorption enhancer into an adhesive layer of a matrix type patch formulation." See col. 2, lines 33-38.

In contrast, the present Applicant has clearly identified the effects of the organic acid salt powder of the claimed size. No person of ordinary skill would have expected, from the prior art cited, that particles of the claimed size (0.1-10 μm) would result in the ion-pair formation which brings superior properties such as improving solubility of the drug to the skin (page 4, lines 9-19) and percutaneous drug-absorbance effect (page 4, line 24 to page 5, line 1). These advantageous effects are clearly demonstrated by the working examples and comparative examples in the present specification.

Therefore one of ordinary skill in the art would not be motivated to use organic acid salt size powder having particle sizes in the claimed range. Thus, the non-obviousness of the present invention vis-à-vis the cited prior art should be affirmed.

In view of the foregoing, withdrawal of the rejections of the claims as unpatentable over JP 08-157365, JP 10-045570 or US patent 5,866,157 under 35 U.S.C. 103 is respectfully requested.

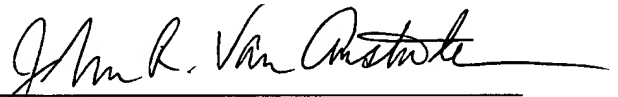
CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this response, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

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